

REMARKS

Rejection Under 35 USC §112, second paragraph

The Examiner has rejected Claims 1-4, 6 and 7 on the ground that they are indefinite for failing to particularly point out and distinctly claim the subject matter which is regarded as the invention. Specifically, the Examiner states that in Claim 1 (line 9), "said detection step lacks antecedent basis." Pending Office Action, page 2. The Applicants, solely in order to advance their business interests, and while retaining the right to prosecute the same or similar claims in the future, have amended Claim 1 to provide proper antecedent basis and to better clarify the metes and bounds of the instant invention by amending independent Claim 1 to replace "...said detection step ..." with "... a capturing step...". Since Claims 2 – 4, 6 and 7 are dependent upon Claim 1, the amendment should also put those claims into position for allowance. In view of the claim amendment the Applicants respectfully request that the rejection be withdrawn.

The Examiner also objects to Claim 20 as being confusing because the Examiner believes that the wording of the claim is directed towards the diagnosis of a symptom of a disease condition rather than a disease condition itself, as recited in the preamble to the claim. The Applicants disagree. However, in order to solely advance the business interests of the Applicants, and while retaining the right to prosecute the same or similar claims in the future, the Applicants have amended Claim 20 to overcome this rejection by replacing the word "diagnosing" with the word "detecting." The Applicants respectfully request that the rejection be withdrawn.

The Examiner has rejected Claims 40 and 41 as being vague and indefinite "because the preamble of these claims do not correlate with the wherein clause" and has additionally rejected Claim 41 for being confusing because "a 'sample' cannot have a symptom." The Applicants disagree. However, solely to advance their business interests and while reserving the right to prosecute the same or similar claims in the future, the Applicants have canceled Claims 40 and 41 making the rejection moot. The Applicants respectfully request that the rejection be withdrawn.

Rejection Under 35 USC §112, first paragraph

The Examiner has rejected Claims 20-23 for failing to comply with the written description requirement. Specifically, the Examiner states “the amendment of Claim 20 does not have support in the specification as originally filed.” The Applicants believe that the amendment to Claim 20, as discussed above, places Claim 20, and the rejected dependent claims, in position for allowance and respectfully request that the rejection be withdrawn.

Rejection Under 35 USC §103

The Examiner has rejected claims 1 - 4, 6 - 11, 13-17, 19 - 23 25 – 26 and 40 – 41 as being obvious in light of Barrows *et al.* (1978) when considered in light of US Patent No. 6,436,721 (to Kuo, *et al.*, and International Patent Publication No. WO 98/33069 (to Sy). This rejection is respectfully traversed.

The Examiner has maintained her obviousness rejection. The basis for the Examiner’s maintained rejection seems to be that although the Barrow technique is not directed to the problems associated with the prozone phenomenon, the Applicants have merely recognized another advantage which would flow naturally from the prior art method. This would seem to almost equate to an inherency type argument in that the Examiner is suggesting that the Applicants have merely identified a feature inherent in the prior art. To this end, the Examiner has stated that the difference between Barrows and the claimed invention is merely the design of the diffusion to take a lateral flow format.

In regards to the pending rejection, the Applicants would like to point out to the Examiner that the development of the present invention is significantly more than merely recognizing an advantage which pre-existed in the Barrows method and effecting this advantage/method in the context of a lateral flow chromatography system rather than a radial diffusion system.

In the first instance, Barrows specifically teach an immunochemical test that exhibits increased sensitivity for human hemoglobin over purely chemical tests such as guaiac which may yield false positive tests for irrelevant components. That is, Barrows, *et al.*, replace the guaiac test with the immunological method in order to overcome limitations inherent in the guaiac based chemical test. However, the present invention represents a new test system design that overcomes limitations of immunological testing, limitations that existed, but did not appear to have been recognized, in the context of the Barrows test.

Specifically, the issue of the prozone phenomenon, being a unique immunological problem, existed in the context of the radial immunodiffusion assay described by Barrows. Barrow's test only overcame the problem of false-positive guaiac results but did not overcome, nor even recognize, immunological prozone-derived false-negative results. In terms of the guaiac related problems, by eliminating the use of guaiac in favor of an immunological test which utilized antibodies specifically directed to hemoglobin, false positive results caused by guaiac cross-reactivity with molecules other than just hemoglobin were avoided. However, depending on the concentration of blood present in a sample which is analyzed by the Barrows methodology, a false-negative result could be unknowingly obtained. Specifically, the existence of either a very low concentration of blood or a very high concentration of blood in a test sample would lead to a false-negative test result due to the action of the prozone phenomenon.

Furthermore, since there is no recognition in Barrows, *et al.*, of the prozone phenomenon, we fail to see how this prior art is in fact relevant to the present invention.

Still further, neither Kuo or Sy discuss the problem of the prozone phenomenon in the context of immunological hemoglobin detection nor do they discuss the problems associated with guaiac based testing of hemoglobin. They both merely disclose more generally the use of lateral flow matrices.

The present invention is more than just the redesign of the Barrows method as a lateral flow chromatography strip. The present invention is 1) the recognition of the significant problem which exists in the context of the prozone phenomenon; 2) the *de novo* design of a test system which overcomes this problem by virtue of a two-part based testing mechanism on a single test strip and; 3) a design which has been created to also avoid the fact that guaiac can interfere with immunological interactions. Such interference results in yet another level of potentially false results.

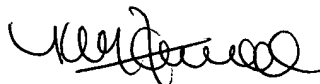
Accordingly, the present invention overcomes a significant problem that would have existed with the Barrows test, but was not recognized at that time, that being the occurrence of the prozone phenomenon and the resultant false negative results which would be obtained where certain concentrations of hemoglobin existed in a biological test sample. The Applicants determined that the only way to effectively overcome the prozone problem was to provide a single step, two-part test process. The present invention also overcomes the problem of guaiac interference with immunological interactions with the single step, two-part process of the present

invention since the interference that one testing system (*i.e.*, guaiac) may exhibit in the context of the other testing system (*i.e.*, immunological) is also avoided. In view of the argument presented above, the Applicants respectfully request that the rejection be withdrawn.

Summary

In light of the above amendment, consideration of the subject patent application is respectfully requested. Any deficiency or overpayment should be charged or credited to Deposit Account No. 500282.

Respectfully submitted,



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